ULLMAN, SHAPIRO & ULLMAN, LLP

COUNSELORS AT LAW
299 BROADWAY, SUITE 1700
NEW YORK, NY 10007
TEL. 212-571-0068
FAX. 212-571-9424
USU@USULAW.COM

ROBERT ULLMAN
STEVEN SHAPIRO*
MARC S. ULLMAN

OF COUNSEL:
MILTON A. BASS
IRVING L. WIESEN

* ADMITTED IN N.Y. & N.J.

TRADEMARK COUNSEL:
Dennis H. Cavanaugh
274 MADISON AVE.
SUITE 300
NEW YORK, NY 10016

WASHINGTON AFFILIATE
James M. Johnstone
1750 K STREET, N.W. -THIRD FL.
WASHINGTON, D.C. 20006

LONDON AFFILIATES
Wedlake Bell
16 BEDFORD STREET
COVENT GARDEN
LONDON WC2E 9HF
ENGLAND

May 7, 1999

Certified Mail, Return Receipt Requested

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA request for Public Comment on the Scope and Nature of FDAMA Authoritative Statement Health Claims

Docket No. 99N-0554

Submitted On Behalf of Metagenics, Inc.

Dear Sir/Madame:

These Comments are submitted on behalf of Metagenics, Inc., ("Metagenics" or the "Company") of San Clemente, California. Metagenics is distributor high quality dietary supplements providing numerous health benefits for consumers. The Company markets its products under its own name, as well as under the Ethical Nutrients, Unipro, MetaBotanica, and MetaPharma brand names.

Metagenics is submitting these Comments in response to a request by the Food and Drug Administration ("FDA" or the "Agency") for public comment concerning the nature of an appropriate definition of what should constitute an "authoritative statement" for purposes of section 403(r) of the Food, Drug and Cosmetic Act ("FDCA"), as amended by the Food and Drug Modernization Act of 1997 ("FDAMA"), which permits the use of health claims based upon "authoritative statements"of appropriate entities within the Federal Government, other than FDA, with responsibility for public health issues.

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At the outset, Metagenics notes that the clear, undisputed purpose of the authoritative statement health claims provision of FDAMA was to create "a less time-consuming and less burdensome alternative for establishing the scientific basis for such claims" than the onerous procedures established by FDA for clearance of conventional health claims. Any final regulation promulgated by the Agency governing the use of authoritative statement health claims must comport with this legislative purpose. Such action can only enhance the public health by permitting the free flow of important, truthful and non-misleading health related information to the American public. Moreover, Metagenics notes that any regulatory action by FDA must be undertaken within the recent decisions by the United States Court of Appeals for the District of Columbia Circuit in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) and the United States District Court for the District of Columbia in Washington Legal Foundation v. Freidman, 13 F. Supp.2d 51 (D. D.C. 1998) ("WLF"), both of which rejected Agency regulations as violative of First Amendment Free Speech principles.

In the March 24, 1999 Federal Register announcement, FDA specifically requests that Comments respond to questions raised by the Agency in three general areas: (1) The scientific basis for authoritative statement health claims; (2) The applicability of existing health claim regulations to authoritative statement health claims; and (3) The substantive nature of any authoritative statement health claims regulations promulgated by FDA. While these Comments will attempt to discuss each of these issues as fully as reasonably practical, Metagenics notes that unless FDA abandons the overly paternalistic theory that "health claims lacking `significant scientific agreement' are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible to exercise any judgment at the point of sale" (See, Pearson,164 F. 3d at 655), any regulations promulgated by the Agency will be rife with the same constitutional defects as those struck down by the Courts in Pearson and WLF.

Issue 1. The Scientific Basis For Claims

Question a. What is an "authoritative statement"?

Plain Language Response: Metagenics believes that the answer to this question is contained within the text of FDAMA. Section 303 of that law amended section 403(r) of the FDCA to permit health claims based upon statements of government entities other than FDA with responsibility for public health issues. Specifically, Section 303 of FDAMA states:

> [A] claim shall be authorized and may be made with respect to a food if --

(i) a scientific body of the United States Government with official responsibility for the health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention), the National Academy of Sciences, or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health related condition to which the claim refers;

* * *

(iv) [Provided] the claim is stated so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

FDA Modernization Act of 1997, Pub. L. No. 105-115, Title 3, Sec. 303, § 403(r)(3) (codified at 21 U.S.C. § 343(r)(3) 1997).

This statutory language is simple and straight forward. It clearly states that in order to be considered "authoritative," the health claim must:

1. based upon an "authoritative statement";

2. of a United States government body with responsibility for health protection or research relating to human nutrition;

3. published;

4. currently in effect; and

5. presented in a manner enabling the public to understand the importance of the claim and its relationship to human nutrition.

Any qualifying requirement beyond these five simple guidelines that might be adopted by FDA will constitute a violation of the plain language of FDAMA and constitute an impermissible effort by the Agency to expand its powers beyond the purview of the FDCA.[1] This point should have been made clear to the Agency from the numerous Comments, including those submitted by Metagenics on September 4, 1998, in response to its response to its promulgation of nine regulations rejecting notifications of authoritative statement health claims. Especially noteworthy among those Comments, were those submitted by The Hon. Dan Burton, Chairman of the House Committee on Government Reform and Oversight, which noted that FDA had grafted "several highly subjective conditions nowhere present in [FDAMA]" onto the definition of an "authoritative statement."

Moreover, FDA should not restrict the use of authoritative statement health claims by viewing any claim for a nutrient for which a health claim already exists as necessarily relating to the claim promulgated by FDA and thereby requiring amendment of that claim. For example, Metagenics submits that statements from the Secretary of Health and Human Services concerning the relationship between calcium intake and increased bone mass in children and young adults and reduced risk of fracture were improperly characterized as relating to the approved osteoporosis health claim. (63 Fed. Reg. 34101, Docket No. 98N-0423). The fact of the matter is that there is a direct relationship between bone mass and fractures – not necessarily related to osteoporosis. For example, in young girls (a population not prone to osteoporosis) just such a relationship was demonstrated in a significant study published in January, 1998. (Goulding, Bone Mineral Density in Girls With Forearm Fractures, 13 Journal of Bone Mineral Research 143 (January, 1998). FDA's inclination to treat all information concerning the relationship between calcium intake and bone health as subsumed within its approved health claim for osteoporosis evidences a myopic view of the benefits of calcium supplementation and is symptomatic of the Agency's overly restrictive view of dietary supplements in general.

Question b. Who defines "authoritative statement"?

Response: Congress has. As discussed in response to the previous question, Metagenics believes that the relevant provisions of FDAMA are simple and straightforward.

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[1] Furthermore, the legislative history of FDAMA makes it clear that the term "authoritative statement" is intended to include all statements of official public health agencies of the Untied States that are issued in order to convey information relating to public health. (See, S. Rep. 105-43 at 49). Metagenics urges that FDA take no action that would curtail the scope of this definition.

That FDA has seen fit to even pose this question suggests that the Agency is seeking some justification to continue its efforts to rewrite FDAMA, and put it self in the position of sole arbiter of what health information should be conveyed to the American public. Metagenics respectfully submits that FDAMA is devoid of any justification for such an effort.

Question c. Who decides if a particular statement is an "authoritative statement?"

Response: In accordance with the plain language of FDAMA, it is FDA's duty to ensure that any particular statement for which it is given notice that it is intended to be used as the basis for an "authoritative statement" health claim satisfies the terms of the statute. To the extent that the Agency is seeking justification for any expansion of its power to review such claims beyond ensuring that the requirements of FDAMA as set forth above are satisfied, none exists. FDA is obligated to uphold the requirements of the FDCA, nothing more, nothing less.

In the event that a scientific body of the United States Government issues an independent declaration that the statement in question is not authoritative, such a declaration, of course warrants considerable weight, and may, indeed, be disposative.

Question d. Is the "context" of a statement in the publication in which it appears relevant to that determination? If so how?

Response: Once again, the answer to this question is contained within the plain language of FDAMA. Section 303 (iv) of FDAMA clearly requires that the claim must be stated in such a manner that it "is an accurate representation of the authoritative statement." The use of out of context, isolated statements from an otherwise contrary publication clearly will not satisfy this requirement.

Moreover, it must be noted that the basic free speech principles enunciated in Pearson and WLF extend only to truthful and non-misleading speech. Metagenics does not disagree with FDA actions to block speech that is neither truthful nor misleading. Such actions do not violate the fundamental First Amendment principles central to the issue of free transmission of important health information to the American public.

Question e. How does the significant scientific agreement standard apply to health claims based on authoritative statements?

Response: It does not. Congress clearly intended to create authoritative statement health claims in order to provide "streamlined procedures . . . to permit more scientifically sound nutrition information to be provided to consumers." These procedures clearly contemplate the use of statements generated by responsible government bodies other than FDA with expertise in the area of public health, without independent FDA review. Any Agency effort to graft the requirement that an authoritative statement health claim must satisfy its onerous significant scientific agreement standard would render 303 of FDAMA superfluous and be beyond the Agency's authority and contrary to law.

This point is enunciated in Comments submitted by Chairman Burton in his letter of August 13, 1998 to Dr. Michael Friedman, Lead Deputy Commissioner which states:

> Congress enacted Section 303 in reaction to FDA's poor track record on the folic acid health claim. FDA's interpretation of the [significant] scientific agreement standard could have contributed to thousands of needless preventable deaths when, in the years following the public recommendations of the Public Health Service and the Centers For Disease Control (associating consumption of folic acid with a reduction in neural tube defect births), FDA continued to prohibit the claim. We sought to prevent that kind of unnecessary event from recurring by enacting Section 303. [FDA's] interim final rules, however, only reinforce the existing censorship effected by the [significant] scientific agreement standard. Consequently, I fully expect that FDA's denial of vital health information to the public will pose a continued threat to the health of the American public.

Issue 2. Existing Regulatory Requirements

Question a. What requirements of 21 CFR 101.13 and part 101, subpart D should we apply to nutrient content claims based on authoritative statements?

Response: Those portions of the regulations that are necessary to ensure that a nutrient content claim is truthful and non-misleading should be applied. This includes those regulations that may restrict certain nutrient content claims due to the presence of other nutrients that are deleterious to the public health.

Question b. What requirements of 21 CFR 101.14 should we apply to health claims based on authoritative statements?

Response: Metagenics believes that only 21 CFR 101.14(a)(5) can validly be applied to FDAMA authoritative statement health claims. This portion of the existing regulations deals with disqualifying levels of potentially deleterious nutrients such as fat, cholesterol and sodium. Application of this regulation to restrict the use of an otherwise valid authoritative statement health claim would seem to be necessary in order to ensure that only truthful and non-misleading health information was transmitted to the American public.

Application of any of the other substantive provisions of 21 CFR 101.14 to authoritative statement health claims would constitute an unlawful effort by FDA to expand its powers of review of such claims. As is fully discussed elsewhere in these Comments, FDAMA clearly does not intend any such review, and, in fact expressly rejects it.

Issue 3. Procedural and Definitional Issues

Question a. Which agencies should we identify as scientific bodies of the U.S. Government with responsibility for public health protection or research directly relating to human nutrition under section 403(r)(2)(G)(i) and (r)(3)(C)(i) of the act?

Response: Once again, the response to this question may be found in the text of the statute itself, which provides that the National Institutes of Health ("NIH") or the Centers for Disease Control ("CDC") or the National Academy of Sciences or any of its subdivisions are to be considered a qualifying "scientific body of the U.S. Government," per se. In addition, Metagenics believes that statements issued by the individual subdivisions of the NIH and the CDC are entitled to a strong presumption that they qualify as authoritative statements under FDAMA. The subdivisions of these scientific bodies are the centers of much of the specialized knowledge of the larger bodies of which they are a part. Frequently, these subdivisions are responsible for the timely dissemination of important health information to the American Public. Unless a statement by one of the individual subdivisions is inconsistent with an express policy position of either the NIH or CDC, Metagenics urges that FDA permit reliance on such a statement for purposes of formulation of "an authoritative statement" health claim.

In addition to these entities which are specifically mentioned in FDAMA, other government bodies with responsibility for public health such as the Department of Agriculture, including the Food and Nutrition Service and the Center for Nutrition Policy and Information; the Department of Health and Human Services (including statements by the Secretary of Health

and Human Services, such as was submitted in connection with Docket No. 98N-0423 for the claim "Calcium consumption by adolescents and adults increases bone density and may decrease the risk of fractures"), and the Office of the Surgeon General warrant consideration as a "scientific body of the U.S. Government" for purposes of authoritative statement health claims.

Question b. Should we provide by regulation that health claims based on authoritative statements may be used in the labeling of dietary supplements?

Response: Yes. There is no rational basis for not expressly recognizing that authoritative statement health claims may be utilized on behalf of dietary supplements. Indeed, a proposal for just such action was set forth by FDA in the January 21, 1999 Federal Register. That proposal, which formally placed dietary supplements on an equal footing with conventional foods for purposes of authoritative statement health claims should be promulgated as soon a practical.

Question c. What should we require that you submit with a notification of a health claim or nutrient content claim based on an authoritative statement?

Response: Once again, this question is answered by the statute itself, and Metagenics queries whether the Agency has some ulterior motive in posing it as part of its request for comment. FDAMA specifically states that the information presented to FDA must consist of:

1. A notice of the claim, which shall include the exact word used in the claim and shall include a concise description of the basis on which the person believes the claim to be based upon an authoritative statement;

2. A copy of the authoritative statement; and

3. A balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers.

No grounds exist upon which FDA may require the submission of any information beyond this statutorily specified data.

Metagenics believes that any final regulation promulgated by FDA should permit the requirement of a presentation of a balanced representation of the scientific literature to be satisfied by the submission of citations to the literature, except where an article, abstract or other publication is not available to the public. Where the cited material is available in the public domain, requiring submission of full texts of studies, books, articles or other publications will be unduly burdensome, and serve no purpose other than the generation of voluminous quantities of paper.

Question d. Should we require you to submit in a notification an analytical methodology for measuring the substance that is the subject of your claims?

Response: No. Any such requirement would be arbitrary and capricious, and without authority under the FDCA. As noted in the preceding response, the statute is clear as to the nature of what must be submitted to FDA in connection with the notification of intended use of an authoritative claim health statement. There is no basis for FDA to graft the requirement of an analytical methodology onto the statute.

To the extent that the Agency is concerned that companies might market products bearing health claims which do not contain the nutrient for which the claim is made, Metagenics submits that FDA has sufficient power for rapid enforcement action against any such product. FDA has always had, and continues to have, the power to take effective enforcement action against any product under its jurisdiction which is misbranded and/or adulterated. Indeed, the marketer and/or manufacturer of any such product is potentially subject to criminal prosecution. No additional hurdles need to be erected or enforcement powers created for FDA to effectively monitor the use of authoritative statement health claims.

Question e. What is a balanced presentation of the scientific literature relating to the subject to which a claim refers that is required under section 403(r)(2)(G)(ii)(III) and (r)(3)(C)(ii)(III) of the act?

Response: As noted in the Joint Explanatory Statement of the Committee of Conference which accompanied FDAMA, a balanced presentation of the scientific literature may include a bibliographic statement of the literature relating to the claim. Such a presentation should include reference to the major scientific studies on the disease or health-related condition/nutrient relationship in existence. While the presentation need not be exhaustive, it should be sufficient for an expert in the field of nutrition to render an opinion on the state of the science at the time the notice is presented to FDA.

Question f. Should FDA keep notifications confidential for 120 days after the date of their submission or should we place them in a public docket upon receipt?

Response. While Metagenics believes that there needs to be some effort undertaken to encourage the development of scientifically valid health claims and to encourage the private study of nutrient/disease or health-related condition relationship, it does not appear that there exists any statutory basis for imposition of a 120-day confidentiality period. Indeed, even if FDA were to suggest that the motive for confidentiality was to encourage such activity, the lack of any provision for exclusivity at the end of the 120-day period would render the imposition of confidentiality irrelevant.

FDA should place notifications of authoritative statement health claims on the public docket as soon as they are received. Such action will foster the fullest possible public participation in the regulatory process.

Question g. If a notification is incomplete or does not support a claim, should we respond to it by letter or by issuing a regulation, and what should be the legal effect of letters were we to use them?

Response. FDAMA provides that use of an authoritative statement health claim may commence 120 following days of notification to FDA unless the Agency issues a regulation prohibiting or modifying the claim. Among the grounds enunciated for such action are the finding that the notification to FDA does not support the claim or is incomplete. Thus, in order for FDA to satisfy only its minimal statutory obligations, issuance of a regulation prohibiting the use of the claim would suffice.

However, in light of the important public health concerns at issue in the area of health claims, Metagenics respectfully submits that utilization of letter responses requesting clarification of data or information, or the submission of additional information in conjunction with notification of FDAMA authoritative claim notifications would be appropriate. Such letters can be issued by FDA with a clear statement that they are without prejudice to any final Agency determination (such as the Agency "Courtesy Letters" presently utilized in connection with structure/function notifications) and may not be an all inclusive listing of the defects in the notification (such as Agency "Warning Letters"). Adoption of this procedure would facilitate the correction of any deficiencies in any otherwise valid notification without the delay that would occur following even the minimal procedures set forth in the Act. In light of the potential

importance of the transmission of valid health claim information to the American public, FDA should take all steps possible to limit any delay of the development of valid health claims.

Conclusion

With the passage of FDAMA, Congress sought to allow authoritative statement health claims and create a "streamlined procedure" whereby it is possible to bypass FDA's unreasonably restrictive "significant scientific agreement" standard. Any regulations promulgated by FDA must recognize Congress' intent. The Agency's statement (as recently as January 21, 1999) that it continues to possess the right to apply the significant scientific agreement standard compels Metagenics to agree with Chairman Burton's observation in his August 13, 1998, letter to Dr. Friedman, when he stated that FDA's position "only reinforce(s) the existing censorship effected by the [significant] scientific agreement standard. I fully expect that FDA's denial of vital health information to the public will pose a continued threat to the health of the American public." FDA must abandon this position and recognize the right of the American public to receive all truthful and non-misleading health information so that it may make educated decisions for itself concerning the maintenance of its well-being.

Respectfully Submitted,

ULLMAN, SHAPIRO & ULLMAN, LLP

Marc S. Ullman

Attorneys for
Metagenics, Inc.
971 Calle Negocio
San Clemente, CA 92673

the right of

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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852